

Interview 2:00pm Today Tues

Response Under 37 C.F.R. § 1.111  
U.S. Appl. No.: 09/582,842

Attorney Docket No.: Q60017

### REMARKS

Claims 1-3, 6-12 and 24-30 are pending in the application and are currently rejected.

#### **I. Claim Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 1-3, 6-12, and 24-30 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification as filed. Specifically, the Examiner contends that the new limitation "and wherein only the avidin portion of the complex is cross-linked" is new matter.

In response to Applicants' arguments in the Second Amendment under 37 C.F.R. § 1.116 filed on August 11, 2003, the Examiner states that the 103 rejections are withdrawn in lieu of the new matter rejection, and that the "art rejection" would be reapplied if the added limitation "and wherein only the avidin portion of the complex is crosslinked" were removed. The Examiner contends that Applicants admit that support for the new limitation "and wherein only the avidin portion of the complex is cross-linked" is inherent in the specification, and further contends that Applicants admit that the specification fails to show clear support. Finally, the Examiner contends that the specification must show clear support on such an "important limitation" of the claimed invention.

#### **II. Our Comments**

Applicants respectfully request reconsideration of the new matter rejection on the following grounds.

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First, while the Examiner indicates that where an amendment is "important," "clear support" must be shown, the MPEP § 2163.07(a) provides differently. The MPEP § 2163.07(a) provides that an application can be amended to recite an inherent property of an invention although the disclosure of this property in the original specification is not "explicit." Therefore, Applicants request that the new matter rejection be withdrawn as the Examiner has applied the Written Description requirement in a legally improper manner.

Second, while Applicants stated in the Second Amendment filed August 11, 2003 that support for the added limitation is "inherent" in the specification, complying with MPEP § 2163.07(a), Applicants nonetheless submit that "clear" support for the phrase "and wherein only the avidin portion of the complex is cross-linked" is found in the specification as follows, although not intending to be exhaustive.

(1) The title of the invention indicates an invention where avidin is crosslinked and does not refer as such to any molecule other than avidin.

(2) The specification at page 4, line 29, shows an initial step of crosslinking avidin to prepare a crosslinked avidin. Since no other components are added to the reaction except the crosslinking reagent and avidin, only avidin can be crosslinked.

(3) The specification at page 7, line 16, states that "crosslinked avidin can be prepared by treating avidin with a crosslinking agent." Since no other reagents are added to the reaction, it is clear that only avidin can be crosslinked.

(4) The specification at page 12, first full paragraph, states that the crosslinked avidin is prepared separately, that is no other molecules are added to the cross-linking reaction.

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Allowable?

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(5) The specification at page 15, line 9, states that the subunits of the crosslinked avidin are covalently bound to each other. The specification makes no similar statement with regard to covalent linkages formed between any other components by crosslinking.

(6) The specification at page 6, lines 25-30 describes that the avidin is crosslinked and the biotin is bound by a biotin-avidin reaction (i.e. biotin and avidin are not bound to each other by crosslinking).

(7) The specification at page 20, Example 1, describes a crosslinking reaction. This reaction only includes streptavidin and the crosslinking reagent glutaraldehyde in a buffer. The reaction is stopped after 4 hours with the addition of sodium borohydride before using the crosslinked avidin product. Therefore, only the avidin can be crosslinked.

Since there is clear support in the specification as filed for the phrase "and wherein only the avidin portion of the complex is cross-linked," and further since "clear support" is not the appropriate Written Description standard, Applicants respectfully request reconsideration and withdrawal of this rejection.

### III. Conclusion

In view of the fact that the section 103 rejections have been withdrawn in view of the Amendment filed August 11, 2003, and in view of the fact that the only remaining rejection is improper, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be

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best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.


Respectfully submitted,

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WASHINGTON OFFICE

**23373**

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Date: March 15, 2004